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10/083,024	02/26/2002	Douglas Alan Miller	45568-00040	4446

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EXAMINER

JACOBSON, TONY M

ART UNIT	PAPER NUMBER
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2644

DATE MAILED: 05/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/083,024

Applicant(s)

MILLER ET AL.

Examiner

Tony M. Jacobson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 16-31 is/are rejected.
- 7) ☒ Claim(s) 13-15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Specification

1. A series of singular dependent claims is permissible in which a dependent claim refers to a preceding claim which, in turn, refers to another preceding claim.

A claim which depends from a dependent claim should not be separated by any claim which does not also depend from said dependent claim. It should be kept in mind that a dependent claim may refer to any preceding independent claim. In general, applicant's sequence will not be changed. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-3, 16, 18-23, 26-29, and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Leysieffer (USPN 6,554,762).
3. Regarding claims 1 and 21, Leysieffer discloses in Fig. 1, an implantable hearing aid (12) with means for measuring its coupling quality, which comprise a signal generator (DSP 13 in combination with microcontroller 17) to output a test signal at a predetermined frequency, that generates at least one electrical signal passing through

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an implanted hearing aid actuator (16); voltage and current measurement logic (25) to measure a voltage and a current of the at least one electrical signal; and a signal processing unit (13) to process the voltage and current measurements to provide an output (19) usable to assess the performance of the hearing aid. The inherent normal method of testing the quality of the coupling of the actuator a component of a patient's auditory system according to the system of Leysieffer would comprise positioning a test measurement device (element 22 of Fig. 1) external to a patient having the implanted actuator; utilizing the test measurement device to obtain at least one impedance measure of the actuator, responsive to an electrical signal passing through the actuator (column 14, lines 44-48 and claim 13) ; and employing the at least one impedance measure to assess the performance of the actuator (claim 1).

4. Regarding claims 2, 3, 22, and 23, Leysieffer discloses at column 6, lines 46-63 that means are provided for objectively determining the quality of coupling between the output transducer (actuator) and the coupled auditory element based on the measured impedance. Objective determination based on measured quantities inherently comprises comparing the measured quantities to a one or more predetermined ranges. Leysieffer discloses at column 13, line 66 through column 14, line 7 that the microcontroller (17) of the implanted hearing aid communicates bi-directionally through the closed skin with an external programming system (22), which can advantageously be a PC-based system with the corresponding programming, processing, display, and administration software. Although Leysieffer does not explicitly disclose the detailed nature of the output provided to the operator of the system, one of ordinary skill in the

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art would conclude that means are included within the programming system to provide a user-interface output, via a display of the PC-based programming system, indicative of whether the measured quantities are within predetermined ranges.

5. Regarding claim 16, Leysieffer discloses at column 14, line 60 through column 15, line 11 that a voltage and a current of the signal applied to the actuator are measured.

6. Regarding claims 18, 19, 27, and 28, Leysieffer discloses at column 8, lines 1-17 that impedance measurements (and thus voltage and current measurements) are made at frequencies extending over the entire transmission frequency range of the output transducer (actuator), which inherently requires providing a plurality of predetermined test signals having different frequencies distributed across a predetermined frequency range for use in generating a corresponding plurality of electrical signals passing through the actuator.

7. Regarding claim 20, Leysieffer discloses at column 8, lines 23-31, means for detecting (and thus identifying) the spectral distribution of resonance frequencies of the transducer in the course of the impedance measured as a function of the frequency of the stimulation signal.

8. Regarding claim 26, as broadly as claimed, any test signal has a frequency that is within some (predetermined) range of a resonant frequency of an actuator.

Additionally, Leysieffer discloses at column 8, lines 23-29 that impedance is measured at resonance frequencies, which inherently requires the signal generator to output test signals at those resonant frequencies.

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9. Regarding claim 29, as described above regarding claims 2 and 3, Leysieffer discloses that means are provided for objectively determining the quality of coupling between the output transducer (actuator) and the coupled auditory element based on the measured impedance. Objective determination based on measured quantities inherently comprises comparing the measured quantities to a one or more predetermined ranges using appropriate means, and testing the quality of the actuator coupling to an auditory element as disclosed by Leysieffer will inherently indicate if the hearing aid is operational and thus will implicitly perform the step claimed.

10. Regarding claim 31, the system of Leysieffer comprises an oscillator (DSP 13) for generating the test signal; a test control processor (microcontroller 17) to set the oscillator to generate the test signal; and a reference transmitter (telemetry system 20) to provide the test signal to the actuator.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 4-12, 17, 24-27, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leysieffer (USPN 6,554,762).

13. Regarding claims 4 and 24, it would have been obvious to one of ordinary skill in the art at the time the present invention was made to compare the measured impedance value obtained by the system of Leysieffer with any desired number of predetermined ranges which are at least partially non-overlapping, utilizing appropriate means, in order to categorize the test results. Further, it would have been obvious to make a plurality of ranges at least partially non-overlapping, since if the ranges were not at least partially non-overlapping, they would be identical and the results of the comparisons would duplicate each other.

14. Regarding claims 5 and 25, one of ordinary skill in the art would conclude that means are included and utilized in the system of Leysieffer to provide an output indicative of whether the measured quantities are within the predetermined ranges, otherwise the results of the measurements would be useless and the device would be non-functional with respect to the desired test function.

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15. Regarding claim 6, Leysieffer discloses at column 8, lines 52-57 that the signal processor (13) generates impedance measuring signals, which inherently would be “predetermined”.

16. Regarding claims 7, 10, 11, and 30, as broadly as claimed, any test signal has a frequency that is within some (predetermined) range of a resonant frequency of an actuator. Additionally, Leysieffer discloses at column 8, lines 23-29 that impedance is measured at resonance frequencies, which inherently requires providing test signals at those resonant frequencies. As described above regarding claims 2, 3, 22, and 23 under the heading “Claim Rejections 35 USC 102”, Leysieffer discloses that means are provided for objectively determining the quality of coupling between the output transducer (actuator) and the coupled auditory element based on the measured impedance. Objective determination based on measured quantities inherently comprises comparing the measured quantities to a one or more predetermined ranges, and testing the quality of the actuator coupling to an auditory element as disclosed by Leysieffer will inherently indicate if the hearing aid is operational and thus will implicitly perform the step claimed in claim 10.

17. Regarding claim 8, Leysieffer discloses in Fig. 11 and describes at column 20, line 64 through column 21, line 13, a partially-implanted hearing aid in which the signal processor is disposed in an external unit, and in which the test signals are inherently transmitted transcutaneously between the external unit and the implanted actuator. Although Leysieffer does not explicitly state that the test signals are transmitted between an external transmitter and a subcutaneous coil, Leysieffer does explicitly

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disclose at column 13, line 66 through column 14, line 3 that the transcutaneous communication of signals between the implanted unit 12 and external system 22 in the fully implanted hearing aid system of Fig. 1 is performed wirelessly by way of an inductive coupling coil. It would have been obvious to one of ordinary skill in the art at the time the present invention was made to utilize the same transmission method in the embodiment of Fig. 11.

18. Regarding claim 9, Official notice is taken that it is notoriously well known in the art to include in an implanted hearing aid an implanted microphone for reception of the external acoustical signals which are to be processed by the hearing aid for presentation to the user of the hearing aid (as disclosed by Leysieffer), and that further, it is well known to supply acoustic test signals to the implanted hearing aid through the implanted microphone in order to test the operation of the hearing aid. It would have been obvious to one of ordinary skill in the art at the time the present invention was made to apply this well-known method to the system of Leysieffer and supply the test signals to the implanted actuator(16) of Fig. 1 through one or more of the implanted microphones (10a-10n).

19. Regarding claim 12, Leysieffer discloses at column 6, lines 54-62 that if the coupling quality of the output transducer (actuator) is judged inadequate, it can be improved. One of ordinary skill in the art would conclude that such improvement would be achieved by repositioning the actuator to achieve a desirable interface.

20. Regarding claim 17, Leysieffer discloses at column 7, lines 41-44 that an impedance measure is computed from the voltage and current measurements. While

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Leysieffer does not disclose that the measured voltage and current are obtained in the (external) test measurement device, the option of transmitting the actuator voltage and current measures to an external test device for subsequent calculation of an impedance therein, as opposed to calculating the actuator impedance within the implanted hearing aid and transmitting the resulting calculated impedance measure to the external test device is an obvious design choice, which does not produce any new or unexpected result. It would have been obvious to one of ordinary skill in the art at the time the present invention was made to calculate the actuator impedance either within the hearing aid or within the external test device as convenient.

Allowable Subject Matter

21. Claims 13-15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

22. The following is a statement of reasons for the indication of allowable subject matter: A method for assessing the coupling performance of an implanted-actuator hearing aid comprising measuring the impedance of the actuator in response to a signal passing through the actuator, in combination with an electrically-operated actuator positioning device is not taught or fairly suggested in the prior art.

Conclusion

23. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

24. Müller (USPN 6,540,661) discloses a variety of arrangements for coupling an implanted driver (actuator) to the ossicular chain.

25. Müller (USPN 6,390,970) discloses various embodiments of a system for positioning and fixing implanted actuators or sensors.

26. Engebretson et al. disclose an implantable hearing aid coupler device with the teaching of matching the mechanical output impedance of the actuator to the mechanical input impedance of the coupled auditory element.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tony M. Jacobson whose telephone number is (703) 305-5532. The examiner can normally be reached on Mon. -Fri. 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Forester W. Isen can be reached on (703) 305-4386. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9314 for regular communications and (703) 872-9315 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-4750.

tmj
May 5, 2003


FORESTER W. ISEN
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